Maryland Board of Pharmacy Public Board Meeting

Meeting Minutes June 21, 2017

Name	Title	Present	Absent	Present	Absent
Board Committee	·				
Ashby, D.	Commissioner	X			
Bouyoukas, S.	Commissioner	X			
Evans, K.	Commissioner	X			
Gavgani, M.	Commissioner/President	X			
Hardesty, J.	Commissioner	X			
Leikach, N.	Commissioner	X			
Morgan, K.	Commissioner		X		
Oliver, B.	Commissioner	X			
Peters, R.	Commissioner	X			
St. Cyr, II, Z. W.	Commissioner/Secretary	X			
Toney, R.	Commissioner	X			
Yankellow, E.	Commissioner		X		
Board Counsel					
Bethman, L.	Board Counsel	X			
Felter, B.	Staff Attorney		X		
Board Staff					
Speights-Napata, D.	Executive Director	X			
Fields, E.	Deputy Director of Operations	X			
Brand, E.	Licensing Manager	X			
Page, A.	Executive Administrative Associate	X			
Logan, B.	Legislation/Regulations Manager	X			
Evans, T.	Pharmacist Inspector	X			

Subject	Party	Discussion	(Assigned to)	Results
I. Executive Committee Report(s)	A.) M. Gavgani, Board President	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.		
		1. M. Gavgani called the meeting to order at 9:42 A.M.		
		2. M. Gavgani requested that Board Commissioners and staff introduce themselves and also informed guests that the meeting agenda and packet materials were available for review. She advised guests that all packets must be returned at the end of the meeting.		
		3. M. Gavgani reminded all guests to sign the guest log, indicating whether they would like continuing education credits.		
	B.) Z. St. Cyr, II, Secretary	4. Review and approval of the May 2017 Public Meeting Minutes.	4. The May minutes should reflect acknowledgement of K. Evans as a new Commissioner. Motion to approve the May 2017 Public Meeting minutes with this amendment by D. Ashby, 2 nd by S. Bouyoukas.	4. The Board voted to approve this motion.
II. A. Executive Director Report	D. Speights- Napata, Executive	1. Operations Updates	An update was provided on personnel vacancies and efforts to fill the positions.	
	Director	2. Meeting Updates	2. A discussion was held on the state's proposed new opioid prescribing policy document for Medicaid patients.	2. D. Speights-Napata will draft a letter to the Governor that expresses the Board's

Responsible

Action Due Date

Subject	Party	Discussion	(Assigned to)	Results
				concerns with the proposed new policy.
		3. Presentations/Discussion a. NABP Meeting	3a. R. Peters and S. Bouyoukas provided a summary of the proceedings of the NABP meeting, held in Orlando, FL.	
		b. Pharmacy Tech Consensus Conference	3b. D. Ashby gave an overview of the Pharmacy Technician consensus conference and industry efforts concerning Pharmacy Technician certification.	
		c. Call Center	3c. D. Ashby also shared information from ASHP's 2017 Harry A. K. Whitney Award Lecture. D. Ashby also shared a complimentary anecdote regarding the dramatic improvement in the Board's Call Center.	
B. Operations Report	E. Fields, Deputy Director/ Operations	1. Management Information Systems (MIS) Unit Updates	1. An update was provided on the new mobile instrument being used by inspectors. It is more efficient, reducing the time needed to complete field inspections.	
		2. Budget Update	2. A report on the budget through May 2017 was provided.	
C. Licensing	E. Brand/ Licensing	1. Unit Updates		
	Manager	2. Monthly Statistics	2. It was noted that this is the renewal period for Distributors, hence the high	

Responsible

Action Due Date

Subject	Party		D	iscussion			(Assigned to)	Results
Bubject	rarty			15Cu55IOII			(rissigned to)	- ACSUIGS
		License	New	Renewed	Reinstated	Total	number reported in this month's	
		Туре					statistics.	
		Distributor	62	508	0	1,256	-	
						,		
		Pharmacy	16	0	0	2,102	-	
						,		
		Pharmacist	34	448	0	11,349	-	
		Vaccination	26	5	0	4,423	1	
		Pharmacy	7	0	0	46	-	
		Intern -						
		Graduates						
		Pharmacy	75	24	0	947		
		Intern -						
		Students Pharmacy	129	259	3	9,795	-	
		Technician	129	259	3	9,195		
		TOTAL	349	1,244	3	29,918	-	
				1,2		25,510		
D. Compliance	Y. Wu,	1. Unit Up	dates					
	Compliance	2. Monthly	v Statis	tics				
	Manager	Complaints & 1	-					
		Complaints &	mvesug	auons:				
		New Complaint						
		Resolved (Including Carryover) – 40						
		Actions within (~			
		Final disciplinar	y action	is taken – I	5			
		Summary Action Average days to						
		Average days to	comple	- U				

Action Due Date

Responsible

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
E. Legislation &	B. Logan,	1. COMAR 10.34.02.03 D Proof of Proficiency in	1. Signed June 23, 2017, with effective	
Regulations	Legislation and Regulations	English 2. COMAR 10 24 18 Continued Education	date of July 3, 2017.	
	Manager	2. COMAR 10.34.18 Continual Education	2. June 5, 2017 effective date.	
		3. COMAR 10.34.37 Pharmacy Permit Holder Requirements — Wholesale Distribution and Non- Resident Pharmacy Operations	3. The Board had considerable discussion on this regulation.	
		4. COMAR 10.34.05.05 Security Responsibility.	4. Discussion centered on this regulation needing to specify either "and" or "or," but not both.	
		5. COMAR 10.34.34.05 Pharmacy Students.	5. Following discussion, a motion was made by D. Ashby, 2 nd by R. Peters to accept the language of this regulation with changes proposed by L. Bethman.	5. The Board voted to approve this motion.
III. Committee Reports A. Practice Committee	R. Peters, Chair	1. HB0880(Chapter 0525)SB0450(Chapter 525) Open Meetings Act – Annual Reporting Requirement, Web Site Postings, and Training	1. Commissioner N. Leikach was nominated to serve as the Board's representative to take the required training.	
		2. a. Contraceptive in Vending Machines	2a. The concept was referred to the Practice Committee.	2. The Board voted to approve this motion.

2. b. Response by Practice Committee

2. c. Emergency Contraceptives Review

2b. The Practice Committee did not support the proposed legislation.

2c. The document provided was perused by Commissioners.

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
Subject	laity	Discussion	(Assigned to)	Results
			Presentations to the Board on this	
			issue were made by Dr. David	
			McBride, from the University of	
			Maryland University Health Center;	
			Kelly Cleland, Research Specialist at	
			Princeton University; and Dr. Sharon	
			Camp, a Maryland resident known as	
			the "Mother of Plan B." All advocated	
			in support of locating emergency	
			contraceptives in vending machines on	
			the University of Maryland campus.	
			Board Counsel, L. Bethman, informed	
			the advocates that under Maryland	
			law, the Secretary of DHMH can	
			provide an exemption to the statute	
			that prohibits the distribution of drugs	
			via a vending machine.	
			via a vending machine.	
			M. Gavgani asked for a motion to send	
			this issue back to the Practice	
			Committee for a recommendation to	
			the Board. Moved by D. Ashby, 2 nd	
			by R. Peters.	
		3. Prep-Proposal Concept Paper- Nominations for	3. This concept paper proposes to	3. The Board voted to
		Health Occupation Boards	allow individuals to self-nominate to	approve this motion.
			Maryland health occupations boards.	
			After discussion that included the	
			motivation behind this effort, R. Peters	
			moved, 2 nd by Z. St. Cyr, II, to refer	
			the matter back to Practice to draft a	
			letter expressing the Board's concerns.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
	•		· • •	
		4. Melissa (Lisa) Thompson, Robison & Cole LLP-Practice Response	4. a. Are "hospital-based clinics" that dispense medications to "their" patients for the patients to take home regulated by the Board of Pharmacy? Answer: The dispensing of medications in hospital-based clinics involves a physician dispensing. This is not a decentralized pharmacy as defined under COMAR 10.34.03.02 B (1). b. May the ordering physician dispense, in a hospital Emergency Department, the medications without the physician having a dispensing permit and without the kiosk being either part of an institutional pharmacy or a decentralized pharmacy? Answer: No, under this scenario the physician would need to obtain a dispensing permit from the Board of Physicians. Motion by committee to approve response as prepared, 2 nd by Z. St. Cyr, II.	4. The Board voted to approve this motion.
		5. Tvine Donabedian Regulatory Affairs Co-op Student, Medisca-Practice Response	5. What Maryland's stance on the upcoming implementation of USP 800? <i>Answer:</i> The Board has not at this time taken an official position regarding USP 800 or its application to pharmacy practice in Maryland. Motion by committee to approve response as prepared, 2 nd by J. Hardesty.	5. The Board voted to approve this motion.

	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned to)	Results
		6. Eswar Abbineni- Telepharmacy-Practice Response	6. Question concerning Telepharmacy in Maryland. <i>Answer:</i> Maryland Pharmacy Act does not currently permit remote supervision of pharmacy technicians or interns. Direct supervision means that "a licensed pharmacist is physically available, notwithstanding appropriate breaks, on-site and in the prescription area or in an area where pharmacy services are provided. Motion by committee to approve response as prepared, 2 nd by D. Ashby.	6. The Board voted to approve this motion.
B. Licensing Committee	D. Ashby, Chair	1. Review of Pharmacist Applications: a. Applicant #110929 - The Board denied the request to waive the MPJE exam on February 16, 2017. Applicant is again requesting the Board to consider waiving the MPJE re-test as a requirement for reinstatement of her pharmacist licensure. Prior to renewing her license for 2014-2016, she contacted the Board to discuss renewal options. The information she was provided was that Maryland does not offer an "inactive" status for pharmacists who no longer practice in the	1a. Motion by D. Ashby to approve request, 2 nd by Z. St. Cyr, II. NOTE: This case led to considerable discussion regarding the need to clarify Board policy and consistently convey it to licensees and permit holders.	1a. The Board voted to approve this motion.

	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned to)	Results
		state of Maryland. However, she was told		
		that she has the option to not renew for the		
		2014-2016 cycle and re-new at any later		
		time. During this discussion, she says that		
		only two requirements for renewal were		
		stated:		
		1. The fee with a penalty amount added;		
		and		
		2. Proof of maintained continuing		
		education credits. She says that it		
		was never mentioned that there would		
		be a potential for additional		
		requirements, such as taking the		
		MPJE, if the renewal did not occur		
		within a certain window.		
		This fact pattern is similar to applicant		
		#110499. In both cases, they claim they		
		were not told of the need to take the		
		MPJE if their application expired more		
		than 2 years earlier. Applicant states had		
		she known this she would have never		
		skipped the renewal cycle. As of August		
		2008, applicant no long lives or practices		
		pharmacy in the state of Maryland. She		
		has an active license in other states and		
		has always maintained appropriate		
		continuing education requirements during		
		this time. Maryland is the applicant's		
		primary state and she says it is very		
		important for her to maintain this license		
		in proper order.		
		Licensing Committee's Recommendation:		
		No recommendation		
		b. G. Lee-Thornton - Requesting approval	1b. Motion to Disapprove the request	1b. The Board voted to
		to act as the Maryland licensed	by D. Ashby, 2 nd by J. Hardesty.	approve this motion.

g	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned to)	Results
Subject	Responsible Party	pharmacist for two non-resident pharmacies. One pharmacy is a non-dispensing, remote telepharmacy for a hospital. The other pharmacy is a specialty dispensing pharmacy. There is a proposed regulation that prohibits a Maryland licensed pharmacist from being employed by more than one non-resident pharmacy. Licensing Committee's Recommendation: No recommendation c. M. Monique - Applicant is requesting to use her current work experience as the Director, US Medical Affairs, Hematology, towards the 1,000 hours of pharmacy service required for licensure. She states that she has worked in the pharmaceutical industry in several different capacities and that all of her roles have allowed her to continue to utilize the skills and knowledge she acquired as a clinical pharmacist. Her duties and responsibilities	1c. Motion by committee to approve committee's recommendation, 2 nd by R. Peters.	1c. The Board voted to approve this motion.
		pharmacy service required for licensure. She states that she has worked in the pharmaceutical industry in several different capacities and that all of her roles have allowed her to continue to utilize the skills and knowledge she acquired as a clinical pharmacist. Her duties and responsibilities include the following, • Lead the development, communication, and implementation of US medical affairs strategy for assigned therapeutic area(s)/product(s) - Hemophilia A/B with Inhibitors		
		and Acquired Hemophilia A.Collaborate with internal stakeholders to provide scientific		

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
Bubject	Tarty	Discussion	(Assigned to)	Results
		input, strategic support, and education/training. Ensure timely development, implementation, maintenance, and medical review of clinical, scientific, and HEOR slide presentations and other resources for use by field medical teams (medical science liaisons [MSLs] and medical and scientific outcomes liaisons [MSOLs]). Coordinate and conduct training for field medical teams and sales force teams. Develop and maintain relationships/partnerships with key opinion leaders (KOLs) and other external stakeholders (i.e., payers), medical/professional organizations, and patient advocacy groups in regards to scientific exchange, research, medical education, and other medical affairs initiatives. Conduct country analyses to identify research and education gaps. Design and/or review and approve regional post-approval studies. Identify research grants that advance the science and knowledge of the biologic basis of inhibitors in Hemophilia A and acquired Hemophilia A.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
Subject	1 arty	Discussion	(Assigned to)	Results
		 Participate in independent medical education (IME) grants review board as voting member. Collaborate with Global Medical Affairs, R&D, and Clinical Research Organizations (CRO) for study site recruitment and support other research-related activities for post-authorization studies. Provide input into product lifecycle planning. Lead product launch activities on behalf of US Medical Affairs team/support marketing and sales organization on product launch activities. Develop budget and provide ongoing planning, reporting and monitoring of executed tactics. Lead the coordination and execution of advisory board meetings to understand data/scientific/educational gaps. Provide scientific support in the development of publications. Participate in select global and regional congresses, symposia, and medical committees. Licensing Committee's Recommendation: Deny d. S. Adesina - Pharmacist is requesting a refund of his license renewal fee that was paid before the expiration date. The 	1d. Motion by committee to approve, 2nd by S. Bouyouakas.	1d. The Board voted to approve this motion.

Subject Party Discussion (Assigned to) Results license expired prior to the completion of the renewal application. Applicant states he was advised that, because his completed application for renewal was not received before the deadline, he had to apply for reinstatement. Licensing Committee's Recommendation: Approve		1 Due Date	
the renewal application. Applicant states he was advised that, because his completed application for renewal was not received before the deadline, he had to apply for reinstatement. Licensing Committee's Recommendation:	Subject	igned to) Results	Discussion
	Subject	Te. The Board voted approve this motion a refund of the plication fees by M.	license expired prior to the completion of the renewal application. Applicant states he was advised that, because his completed application for renewal was not received before the deadline, he had to apply for reinstatement. Licensing Committee's Recommendation: Approve e. Applicant #110499 - Applicant is requesting to have the MPJE exam waived and the fees for reinstatement application refunded under the advisement of the Board not to renew her pharmacist licensure in 2015. The timing of her application suggests that she waited until right after the expiration of her license to seek reinstatement. She claims that no one told her that if she sought reinstatement she would have to take another exam. Similar fact pattern as Applicant #110929. Licensing Committee's Recommendation: No recommendation 2. Review of Pharmacy Intern Applications: NONE 3. Review of Pharmacy Technician Applications: NONE

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
Subject	1 arty	Discussion	(Assigned to)	Results
		 6. Review of Pharmacy Technicians Training Programs: a. Giant Eagle Technician Training Program - This program and examination were originally approved in 2009. The company recently submitted an updated program description. The Board voted to not approve the program on May 17, 2017. The company submitted additional documentation and a request for approval 	6a. Motion by committee to approve, 2 nd by D. Ashby.	6a. The Board voted to approve this motion.
		of its program and examination. Licensing Committee's Recommendation: Approve b. Ashworth College Technician Training Program - This item was added to the agenda after the Licensing Committee met and was reviewed by the Chairman. The school seeks approval of its program and examination. Licensing Committee's Recommendation: No recommendation.	6b. Motion by S. Bouyouakas to approve, 2 nd by D. Ashby.	6b. The Board voted to approve this motion.
		 7. New Business: a. Technician Application Edit - Disciplinary Committee wants to add "job title" in the Employment Information section for all technician applications. Licensing Committee's Recommendation: Approve 	7a. Motion by committee to approve, 2 nd by D. Ashby.	7a. The Board voted to approve this motion.

Subject	Responsible Party	Discussion	Action Due Date (Assigned to)	Results
Sasjeet	2 512 5	2.004.00.70.7	(LEUSEBLEW VO)	200000
		b. INO Therapeutics - Company is requesting an extension of the renewal period pending the receipt of background check results. Application was received May 24, 2017. Licensing Committee's Recommendation: No recommendation	7b. Following discussion, a motion to accept a background check submitted by the company within the past year to another jurisdiction was made by D. Ashby, 2 nd by S. Bouyoukas.	7b. The Board voted to accept this motion.
		c. Merchant Gases/Airgas - Company is requesting an extension of the renewal period pending the receipt of background check results. Application was received May 24, 2017. <u>Licensing Committee's Recommendation:</u> No recommendation	7c. Motion to accept a background check submitted by the company within the past year to another jurisdiction was made by D. Ashby, 2 nd by S. Bouyoukas.	7c. The Board voted to accept this motion
		d. Smiths Medical - Company is requesting an extension of the renewal period pending the receipt of background check results. Application was received May 24, 2017. Licensing Committee's Recommendation: No Recommendation	7d. Motion to accept a background check submitted by the company within the past year to another jurisdiction was made by D. Ashby, 2 nd by S. Bouyoukas.	7d. The Board voted to accept this motion
C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update: The PR Committee report was provided by Z. St. Cyr, II, in the absence of the Committee Chair.		
		1. CE Breakfast	1. One of the CE speakers, Dr. Gorelick from the University of Maryland, requests a \$300.00 honorarium to speak at the Board's CE breakfast. Dr. Gorelick's usual speaking fee is \$1,500.00. None of the other speakers at this year's CE breakfast are requesting a speaking fee	1. The Board voted to approve this motion.

	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned to)	Results
			and the Board has never paid speakers at prior CE breakfasts. Board approval is needed to authorize the speaking fee requested this year. Motion by Committee to approve the honoraria, 2^{nd} by R. Toney.	
		2. Former Board member Farewell Dinner	2. August 24 th is the date selected for the former Board member farewell dinner. Location and cost will be forthcoming. Board members were asked to save the date on their calendars.	2. The Board gave tacit approval to moving forward. It was noted that many plan to take vacations in August so the PR Committee should contact the former Board members ASAP to lock in the date and, if it works for everyone, proceed with securing a location.
		3. Joint MPhA/BOP Webinar	3. Concerns were raised about the content of the medical error CE webinar, particularly whether it comported with MD laws since it is produced by the GA BOP. Other concerns were noted about the "appearance" of a conflict of interest by partnering with one of the Pharmacy communities of interest on this project.	3. This matter was tabled until the Board's July meeting in order to give Linda an opportunity to review the content of the webinar.
D. Disciplinary	K. Morgan, Chair	Disciplinary Committee Update: None at this time.		

	Responsible		Action Due Date	
Subject	Party	Discussion	(Assigned to)	Results
E. Emergency		Emergency Preparedness Update:		
Preparedness		1. Commissioner N. Leikach is the newly		
Task Force		appointed Chair of the Emergency Preparedness Task Force.		
		2. The Task Force is revisiting the frequency of its meetings.		
IV. Other	M. Gavgani,			
Business & FYI	President			
V. Adjournment	M. Gavgani,	M. Gavgani asked for a motion to close the Public	Motion to close the Public Board	The Board voted to
	President	Meeting and open a Closed Public Session.	Meeting by D. Ashby, 2 nd by S. Bouyoukas.	approve this motion.
		M. Gavgani convened a Closed Public Session for		
		the purpose of engaging in medical review		
		committee deliberations regarding confidential		
		information in applications in accordance with the		
		Open Meetings Act, General Provisions Article,		
		Section 3-305 (b) (7) and (13).		
		The Open Public Session was adjourned at 12:34		
		P.M. and, immediately thereafter, M. Gavgani		
		convened an Administrative Session for purposes of		
		discussing confidential disciplinary cases. With the		
		exception of cases requiring recusals, the Board		
		members present at the Public Meeting continued		
		to participate in the Administrative Session.		